K090013

APR 21 2009

5 510(k) Summary

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Submitter:	Chempaq A/S Hirsemarken 1 B 3520 Farum Denmark
Contact Person:	Lone Hoffensets Quality Assurance Manager Chempaq A/S Hirsemarken 1 B 3520 Farum Denmark Phone 011-45 44390500 Fax 011-45 44390539 Email: lh@chempaq.com
Date Prepared:	December 17, 2008
Trade Name:	Chempaq XBC Analyzer
Classification:	21 CFR 864.5220
Product Codes:	GKZ
Predicate Device:	Chempaq XBC Analyzer
Device Description:	Automated differential cell counter
Intended Use:	The Chempaq XBC Analyzer is an in vitro diagnostic method intended for the quantitative determination of the concentration of white blood cells ("WBC"); granulocytes ("GRN"); lymphocytes ("LYM"); monocytes ("MON"); and total hemoglobin ("HGB") in whole-blood samples (finger stick or venous sample). The Chempaq XBC Analyzer is indicated for use in: clinical laboratories, and for point-of-care hematology determinations in doctors' offices or by healthcare professionals in hospital settings to identify and classify one or more of the formed elements of blood.

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Functional and Safety Testing:	Chempaq XBC Analyzer uses a single-use, reagent cassette (cartridge) called a "PAQ" which designates "Particle Analyzer and Quantifier". Blood is placed into the PAQ inlet and then the PAQ is placed into the Reader (instrument). Bench tests were done to demonstrate correct function of: • Quality Control Cassette (QCC) for testing of the PAQ electrical connection and Hemoglobin photometric function in the QCC mode. • Liquid Quality Controls (LQCs) with White Blood Cell (WBC) PAQs with the Analyzer in the LQC mode • Linearity materials with the Analyzer in the Linearity mode using WBC PAQs. • Associated print-out of LQC, QCC, Linearity, and patient ID (from bar code scanner). Bench testing was done to show the Analyzer detected mismatches such as inserting the WBC PAQ in the QCC mode or the QC Cassette in the WBC mode. Bench performance testing was done to show that all WBC functionality was uncompromised by the modifications. Software verification and validation was done on all added functionality including code reviews and direct testing of software functionality (e.g. that correct information was shown on the Analyzer LCD depending on the mode selected).
Conclusion:	Results of testing demonstrate that the modifications to the Chempaq XBC Analyzer did not modify white blood cell or hemoglobin measurement functionality, that the added functionality performs as intended, and that potential risks (such as mismatching of PAQ/QCC and test mode) have been mitigated by software changes to detect such mismatches to deliver an error message and prevent reporting of results. We conclude that the modified Chempaq XBC Analyzer is as safe and effective as, and performs as well as, its unmodified version (predicate).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Chempaq A/S
c/o Mr. Lone Hoffensets
Quality Assurance Manager
Hirsemarken 1 B
3520 Farum
Denmark

APR 21 2009

Re: k090013
Trade/Device Name: Chempaq XBC Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: April 06, 2009
Received: April 09, 2009

Dear Mr. Hoffensets,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing

quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K090013

Device Name: Chempaq XBC Analyzer

Indications For Use:

The Chempaq XBC Analyzer is an in vitro diagnostic method intended for the quantitative determination of the concentration of white blood cells ("WBC"); granulocytes ("GRN"); lymphocytes ("LYM"); monocytes ("MON"); and total hemoglobin ("HGB") in whole-blood samples (finger stick or venous sample).

The Chempaq XBC Analyzer is indicated for use in: clinical laboratories, and for point-of-care hematology determinations in doctors' offices or by healthcare professionals in hospital settings to identify and classify one or more of the formed elements of blood.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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